K062098

510(k) Summary of Safety and Effectiveness

Date: February 2, 2007

FEB - 5 2007

Submitter: Patient Monitoring Division
Datascope Corp.

Contact Person: Kathleen Kramer
Supervisor, Clinical & Regulatory Affairs
Patient Monitoring Division
Datascope Corp.
Telephone: (201) 995-8169
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Device trade name: Spectrum™ Monitor

Common/usual name: Multi-parameter patient monitor (with Arrhythmia Detection or Alarms)

Classification names:

21 CFR 868.1400 -Analyzer, Gas, Carbon-Dioxide, Gaseous-Phase
21 CFR 870.1025- Arrhythmia detector and alarm
21 CFR 870.1110- Blood Pressure computer
21 CFR 870.1130- Non-invasive blood pressure measurement system
21 CFR 870.1425- Programmable diagnostic computer
21 CFR 870.1435 - Single-function, pre-programmed diagnostic computer
21 CFR 870.2300- Cardiac Monitor (Incl. Cardiotachometer and rate alarm)
21 CFR 870.2700- Oximeter
21 CFR 880.2910- Monitor, Temperature (with probe)

Predicate Devices: K031849 Spectrum Monitor
K051400 Datex Ohmeda S/5™ Anesthesia Monitor with L-ANE05 and L-ANE05A Software

Device Description: The Spectrum Monitor, which is the subject of this submission, is a modified version of the Datascope Spectrum Monitor, which was previously cleared by FDA under K031849, on September 9, 2003. There have been no significant changes to the Spectrum Monitor since its clearance. At this time, Datascope Corp. has added a new parameter to the device's monitoring capabilities, the measurement of Bispectral Index (BIS) via an interface to the Aspect Medical System's BISx™ module (K040183).

The Spectrum Monitor is a device that is used to monitor, display, trend and print a patient's physiological parameters. The device has a 12.1 inch color display and has a standard configuration of 3 or 5 lead ECG, Masimo SET® SpO_2, Non-Invasive Blood Pressure (NIBP), Respiration, Continuous Temperature and IV Drug Calculations. Optional software includes ST and Arrhythmia Analysis. Optional hardware features include View12 ECG Analysis Module (which includes ST Arrhythmia and 12 Lead interpretation), up to 4 Invasive Blood Pressure Channels, Microstream® CO_2, Anesthetic Gases, Nellcor Oximart® and Oximax® SpO_2, a second temperature source, dual trace recorder, and Cardiac Output.

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A comprehensive calculation package, including Hemodynamic Calculations, is available if the Spectrum is equipped with an External Parameter Module.

Digital displays are provided for Heart Rate, NIBP, SpO_2, Respiration Rate, and Temperature. Optional digital displays are provided for up to four Invasive Blood Pressure, Anesthetic Agents, O_2, and N_20, ST, CO, CO_2, and BIS. The optional internal recorder provides hard copies of all digital data and waveforms, as well as trend information.

Bispectral Index (BIS) is continuous measure of the effects of certain anesthetic and sedative agents on a patient's brain. The Aspect BISx module monitors the hypnotic state of the brain based on acquisition and processing of EEG signals. It processes the raw EEG signal to produce Aspect's proprietary BIS Index, a single value that is correlated with the patient's level of hypnosis. The BISx mates on one side with a patient interface cable, which attaches to Aspect's BIS sensors, and on the other side with the Spectrum Monitor, where the BIS Index is displayed on the integrated display.

Intended Use:

The Spectrum Monitor is intended for intra hospital use under the direct supervision of a licensed healthcare practitioner. The indications for use for the Spectrum Monitor include the monitoring of the following human physiological parameters:

- ECG waveform derived from 3, 5 or 12 lead measurements
- Heart Rate derived from selected sources (ECG, SpO_2, IBP, NIBP)
- Pulse Oximetry (SpO_2)
- ST Segment Analysis derived from 3, 5 or12 ECG lead measurements
- Arrhythmia Detection derived from 3, 5 or 12 ECG lead measurements
- Interpretation of Resting 12 lead ECG
- Non Invasive Blood Pressure (NIBP)
- Invasive Blood Pressure (IBP) - up to four (4) channels
- Cardiac Output
- Respiration Rate/waveform derived from ECG or CO_2
- CO_2, inspired and end tidal microstream/waveform
- Temperature - up to two (2) channels
- Hemodynamic Calculations
- IV Drug Calculations
- Bispectral Index (BIS)

The target populations are adult, pediatric and neonate with the exception of:

- Arrhythmia detection, ST Segment Analysis, Cardiac Output, Hemodynamic Calculations, Pulmonary Artery Wedge Pressure measurements, and
- Interpretation of Resting 12 Lead ECG and IV Drug Calculations, for which the target population is adult only.
- Bispectral Index. The BISx is intended for use under direct supervision of a licensed healthcare practitioner or by personnel trained in its proper use. It is intended for use on adult and pediatric patients within a hospital or medical facility providing patient care to monitor the state of the brain by data acquisition of EEG signals. Note: the clinical utility, risk/benefit, and application of this device have not undergone full evaluation in the pediatric population.

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The Bispectral Index from available information is a complex technology, intended for use only as an adjunct to clinical judgment and training.

The BIS may be used as an aid in monitoring the effects of certain anesthetic agents. Use of BIS monitoring to help guide anesthetic administration may be associated with the reduction of the incidence of awareness with recall in adults during general anesthesia and sedation.

The Spectrum Monitor has the capability of interfacing with Datascope's Intra Aortic Balloon Pumps, Central Stations, and Gas Module products.

Technology: The Spectrum Monitor is substantially equivalent to the Spectrum Monitor (K031849) and the Datex Ohmeda S/5™ Anesthesia Monitor with L-ANE05 and L-ANE05A Software.

Test Summary: Datascope's product development process required that the following activities be completed during the development of the Spectrum Monitor:

- $ Requirements specification review
- $ Software testing
- $ Code design and code reviews
- $ EMC testing
- $ Safety testing
- $ Software validation

Conclusion: The results of all testing demonstrate that the Spectrum Monitor is as safe, as effective, and performs as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Datascope Corporation
c/o Ms. Kathleen Kramer
Supervisor, Clinical and Regulatory Affairs
Patient Monitoring Division
800 MacArthur Blvd.
Mahwah, NJ 07430

Re: K062098
Trade Name: Spectrum Monitor, Model 0998-00-1000-XXXX
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm (Including ST-Segment Measurement and Alarm)
Regulatory Class: Class II (two)
Product Code: MHX
Dated: February 1, 2007
Received: February 2, 2007

Dear Ms. Kramer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts

800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Lechner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE STATEMENT

510(k) Number (if known): K062098

Device Name: Spectrum Monitor

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Welch

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K062098